AAMI Standards Monitor Online
26 January 2024

STANDARDS UPDATE

NEW! We have completed transitioning our standards groups to the NEW AAMI StMP (Standards Management Platform) platform! Information is available here.

Join us

The inaugural **AAMI neXus: A Global Event Advancing Medical Device Standards Development, Adoption, and Application** February 20-23, 2024, in Washington, DC! If you are actively involved or want to be involved in the development and adoption of medical device standards as a manufacturer, regulator, or healthcare professional, AAMI neXus will offer you unparalleled engagement opportunities and information. At AAMI neXus you will hear directly from and interact with the industry and regulatory leaders who are driving both **Development** and **Adoption** of existing standards, as well as planning future standards works. This is your chance to get involved and help shape the future of medical device standards!

AAMI Standards Insider

Check back soon, for the next AAMI Standards Insider webinar date. The **one-hour FREE webinar** provides news and updates about AAMI's standards program and portfolio. Registration for the upcoming webinars and recordings of past webinars in the series is available on the webpage.

Publications

REAFFIRMED! AAMI TIR12:2020/(R)2023, Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers. Click here for more information.

REAFFIRMED! AAMI TIR17:2017/(R)2023, Compatibility of materials subject to sterilization. Click here for more information.

REAFFIRMED! AAMI/ISO TIR11137-4:2022/(R)2023, Sterilization of health care products—Radiation—Part 4: Guidance on process control. Click here for more information.

REAFFIRMED! ANSI/AAMI/ISO 10993-3:2014/(R)2023, Biological evaluation of medical devices—Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity. Click here for more information.

REAFFIRMED! ANSI/AAMI/ISO 10993-5:2009/(R)2022, Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity. Click here for more information.

REAFFIRMED! ANSI/AAMI/ISO 10993-13:2010/(R)2019, Biological evaluation of medical devices—Part 13: Identification and quantification of degradation products from polymeric devices. Click here for more information.

REAFFIRMED! ANSI/AAMI/ISO 10993-14:2001/(R)2019, Biological evaluation of medical devices—Part 14: Identification and quantification of degradation products from ceramics. Click here for more information.

REAFFIRMED! ANSI/AAMI/ISO 10993-16:2020/(R)2022, Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables. Click here for more information.

REAFFIRMED! AAMI/ISO TIR10993-20:2006/(R)2021, Biological Evaluation Of Medical Devices — Part 20: Principles And Methods For Immunotoxicology Testing Of Medical Devices. Click here for more information.

NATIONAL STANDARDS

AAMI Call for Comments

If you would like to comment on one of the draft documents listed below, contact the individual indicated by email to receive a PDF copy of the draft. These copies are free.

Published documents proposed for reaffirmation can be purchased from the AAMI Store.

Comments due 29 January 2024

AAMI/ISO 17665:202X, Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices. (proposed identical national adoption of ISO 17665:202X, Ed. 2) This second edition cancels and replaces the first edition of ISO 17665-1:2006, ISO/TS 17665-2:2009 and ISO/TS 17665-3:2013, which have been technically revised. This standard provides requirements for the development, validation, and routine control of moist heat sterilization processes for medical devices. It also contains guidance which is intended to explain the requirements set forth in the normative sections. The guidance given is intended to promote good practice related to moist heat sterilization processes according to this document. The application within industrial and health care settings is considered. Contact: Mike Miskell

AAMI/ISO 81060-3:202X/Ed.1, Non-invasive sphygmomanometers — Part 3: Clinical investigation of continuous automated measurement type. (proposed identical national adoption of ISO 81060-3:2022) This document specifies the requirements and methods for the clinical investigation of continuous automated non-invasive sphygmomanometers used for the measurement of the blood pressure of a patient. This document covers both trending continuous automated noninvasive sphygmomanometers

and absolute accuracy continuous automated non-invasive sphygmomanometers and focuses solely on requirements for the clinical investigation. This document does not cover usability aspects such as the form and manner of the data display or output and does not specify a numerical threshold on the minimum output period. Contact: Ladan Bulookbashi

Comments due 18 February 2024

AAMI TIR66/Ed.1 - Guidance for the creation of physiologic waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms. (reaffirmation of an American National Standard). This document provides guidance to MANUFACTURERS that change existing or create new ALARM SYSTEM algorithms as to how to create evidence that demonstrates a reasonable assurance of the safety and efficacy of the algorithm. This document also provides guidance to authorities having jurisdiction for the assessment of such evidence. Contact: Rachel Ann Porter

Comments due 19 February 2024

AAMI/ISO 10993-17:202X/Ed.2, Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents (identical national adoption of ISO 10993-17:2023) This document specifies the process and requirements for the toxicological risk assessment of medical device constituents. The methods and criteria used to assess whether exposure to a constituent is without appreciable harm are also specified. The toxicological risk assessment can be part of the biological evaluation of the final product, as described in ISO 10993-1. The process described in this document applies to chemical characterization information obtained in line with ISO 10993-18. When a toxicological risk assessment of either the compositional information or analytical chemistry data (e.g. extractable data or leachable data) are required to determine whether the toxicological risks related to the constituents are negligible or tolerable. Contact: Amir Aboutaleb or Matt Williams

AAMI/ISO 11737-1, Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products (reaffirmation of an American National Standard). This document specifies requirements and provides guidance on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product, component, raw material or package. Contact: Mike Miskell

Comments due 11 March 2024

AAMI ST24, General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities (revision of an American National Standard). Covers minimum labeling, safety, performance, and testing requirements for ethylene oxide sterilizers that are intended for general-purpose use in health care facilities and that have automatic controls. It also covers labeling, product composition, and container requirements for ethylene oxide

sterilant sources, as well as labeling, performance, safety, and installation requirements for ethylene oxide emission control systems. Contact: Tommy Kim

AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities* (revision of an American National Standard) This standard provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for use in hospitals and other health care facilities. These guidelines are intended to assist health care personnel in the safe and effective use of gaseous chemical sterilizing systems, LCSs/HLDs, and associated equipment. Contact: Tommy Kim

New Work

AAMI SM-WG05, Medical Device Security Working Group. The working group is developing a new consensus report (CR) with the title *Security Risk Estimation for Medical Devices*. This consensus report will provide guidance for security risk estimation within the context defined by ANSI/AAMI SW96: 2023 *Standard for medical device security—Security risk management for device manufacturers*. Contact: Amir Aboutaleb or Matt Williams.

Consensus Body Members Needed

The committees listed below are seeking new members in the indicated stakeholder interest category to participate in the development of their documents. Definitions of the various stakeholder groups are:

Industry: *A member of a consensus body who, as an individual or organizational representative, is involved in the commercial production, promotion, sale, use or distribution of materials, products, systems, or services covered in the scope of technical documents developed by AAMI shall be classified as an Industry Interest stakeholder. Individuals in this interest category include manufacturers, those involved in supply chains, employees of test labs or commercial labs, industry consultants, etc.*

User: *A member of a consensus body who, as an individual or organizational representative, purchases, utilizes or receives the materials, products, systems, or services covered in the scope of technical documents developed by AAMI in the delivery of healthcare shall be classified as a User Interest stakeholder. Individuals in this interest category include clinicians, employees or representatives of Healthcare Delivery Organizations, clinical consultants, patients, etc.*

Regulatory: *A member of a consensus body who, as an individual or organizational representative, is involved in the regulation of the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI shall be classified as a Regulatory Interest stakeholder. Individuals in this interest category would include those representing federal, state, local, foreign, or other government entities.*

General interest: *A member of a consensus body who, as an individual or organizational representative, has a general direct and material interest in the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI and who does not fit into any of the preceding categories shall be classified as a General Interest stakeholder. Individuals in this category would include noncommercial academicians, noncommercial researchers, patient or consumer advocates, representatives of accrediting organizations, representatives of other organizations, etc.*

Other Interest: *A member who does not fit into any of the preceding interest categories but who still has an identifiable material interest in, or specialized knowledge of the materials, products, systems, or services covered in the scope of technical documents developed by AAMI in the delivery of healthcare shall be classified as an Other Interest stakeholder. The particular interest shall be declared and documented.*

Please contact the staff person indicated for more information on how to join.

AAMI AI, Artificial Intelligence Committee. AAMI is seeking user, regulatory, and general interest members to participate in the development of a new standard, AAMI AI120 – *Bias Management for Machine Learning (ML) Systems*. Contact: Rachel Porter

AAMI BE-WG2, Degradation aspects related to biological testing Working Group. AAMI is seeking user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-9:2019, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products* and ISO/TS 37137-1:2021, *Biological evaluation of absorbable medical devices — Part 1: General requirements* Contact: Amir Aboutaleb or Matt Williams

AAMI BE-WG8, Irritation and sensitization Working Group. AAMI is seeking user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-10:2021, *Biological evaluation of medical devices — Part 10*. Contact: Amir Aboutaleb or Matt Williams

AAMI BE-WG11, Allowable limits for leachable substances Working Group. AAMI is seeking user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-17:2023, *Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents*. Contact: Amir Aboutaleb or Matt Williams

AAMI BE-WG12, Sample preparation and reference materials Working Group. AAMI is seeking user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-12:2021, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*. Contact: Amir Aboutaleb or Matt Williams

AAMI BE-WG19, Tissue Product Safety Working Group. AAMI is seeking industry, user, general interest, and regulatory members for the newly formed working group to provide input on ISO TC/194/WG 19 activities. Contact: Amir Aboutaleb or Matt Williams

AAMI BG, Blood/Gas Exchange Device Committee. The committee is seeking user, industry, and general interest/regulator members to participate in the revision of ISO 7199, C*ardiovascular implants and artificial organs — Blood-gas exchangers Blood-gas exchangers and* to provide input on ISO TC150/SC2/WG4 activities Contact: Jill Zajac

AAMI BP, Blood Pressure Monitoring Committee. The committee is seeking regulatory, user and general interest members to participate in the reaffirmation and future revision of AAMI BP22-1994 (R2016), *Blood pressure transducers.* Contact: Ladan Bulookbashi

AAMI CI, Cochlear Implants Committee. The committee is seeking industry, regulatory, and general interest members to participate in the reaffirmation and future revision of AAMI CI86-2017, *Cochlear implant systems—Requirements for safety, functional verification, labeling and reliability reporting*. Contact**:** Ladan Bulookbashi

AAMI CN, Small Bore Connectors Committee. The committee is seeking user, regulatory, and general interest members to participate in the reaffirmation and future revision of AAMI/ISO 80369-5, *Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications*; and in the expedited adoption of AAMI/ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*. Contact: Colleen Elliott

AAMI CP, Combination Products Committee. The committee is seeking user, regulatory, and general interest/regulator members to contribute to the development and review of various TIRs Contact: Jill Zajac

AAMI CV, Cardiac Valves Committee. The committee is seeking user, industry, and general interest/regulator members to participate in the US adoption of amendments to ISO 5840-1:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements;* ISO 5840-2:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes;* and ISO 5840-3:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques;* and the revision of ISO 5910:2018, *Cardiovascular implants and extracorporeal systems—Cardiac valve repair devices.* Contact: Jill Zajac

AAMI DPC-10, Needles Working Group. The committee is seeking user, industry, and general interest/regulator members to contribute to the development of the U.S. positions towards the revisions of ISO 9626:2016, *Stainless steel needle tubing for the manufacture of medical devices* and ISO 7864:2016, S*terile hypodermic needles for single use*. Contact: Sam Alameda

AAMI EQ-WG01, Healthcare Technology Management (HTM) Program Management working group. The working group is seeking general interest, industry, and regulatory members to participate in the

revision of ANSI/AAMI EQ56:2013, Recommended practice for a medical equipment management program. Contact: Mike Miskell

AAMI EQ-WG04, Alternative Equipment Maintenance Working Group. The working group is seeking industry, regulatory and general interest members to participate in the development of AAMI EQ103/Ed.1, *Alternative equipment maintenance in healthcare delivery organizations*. Contact: Mike Miskell

AAMI EQ-WG05, HTM Education Programs Working Group. The working group is seeking industry, regulatory and general interest members to participate in the development of AAMI EQ110/Ed.1, *Guidance for health care technology management education programs.* Contact: Mike Miskell

AAMI HF, High Frequency Therapeutic Device Committee The working group is seeking regulatory, user and general interest members to participate in the adoption project for IEC 60601-2-2:2017/AMD1:2023, *Amendment 1 - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*. Contact: Ladan Bulookbashi

AAMI HIT-WG01, Health IT Risk Management Working Group. The working group is seeking user, general interest, and regulatory members to participate in the development of AAMI HIT1000-3/Ed.1, *Safety and effectiveness of health IT software and systems—Part 3: Application of risk management*. Contact: Amir Aboutaleb or Matt Williams

AAMI HIT-WG02, Health IT Quality Systems Working Group. The working group is seeking user, general interest, and regulatory members to participate in the development of AAMI HIT1000-2/Ed.1, *Health IT software and systems—Part 2: Application of quality systems principles and practices*. Contact: Amir Aboutaleb or Matt Williams

AAMI HIT-WG03, Health IT Usability Working Group. The working group is seeking user, general interest, and regulatory members to participate in the development of AAMI HIT1000-4/Ed.1, *Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering*. Contact: Amir Aboutaleb or Matt Williams

AAMI IP, Implantable Infusion Pumps Committee The working group is seeking industry, regulatory, user and general interest members to participate in the adoption project for ISO 14708-04:2022 (Ed.2), *Implants for surgery—Active implantable medical devices—Part 4: Implantable infusion pumps*. Contact: Ladan Bulookbashi

AAMI MC, Mechanical Circulatory Support Systems Committee. The committee is seeking user, industry, and general interest/regulator members to participate in the development of documents under

ISO/TC150/SC2/WG2 including the early revision of ISO 14708-5:2020, *Implants for surgery — Active implantable medical devices — Part 5: Circulatory support devices*. Contact: Jill Zajac

AAMI NS-WG02, Implantable neurostimulator Working Group The working group is seeking regulatory, user and general interest members to participate in the reaffirmation of ANSI/AAMI/ISO 14708-3:2017, *Implants for surgery—Active implantable medical devices—Part 3: Implantable neurostimulators*. Contact: Ladan Bulookbashi

AAMI NS-WG03, Transcutaneous electrical stimulator Working Group The working group is seeking industry, regulatory, user and general interest members to participate in the reaffirmation and future revision of AAMI NS4-2013 (R2017), *Transcutaneous electrical nerve stimulators*. Contact: Ladan Bulookbashi

AAMI QM-WG02, General aspects from medical devices This working group is seeking user and general interest/regulatory members to participate in the national adoption of ISO 20417, *Medical devices — Information to be supplied by the manufacturer.* Contact: Amanda Benedict

AAMI RD, Renal Disease and Detoxification Committee. The committee is seeking user, and general interest/regulator members to participate in the development of new TIRs including backflow prevention, wall boxes, and water distribution loops; a TIR on empty bed contact time calculation and carbon sizing, and input on the adoption of the ISO 23500:2024, *Preparation and quality management of fluids for haemodialysis and related therapies series standards: Part 1: General requirements*; *Part 2: Water treatment equipment for haemodialysis applications and related therapies*; *Part 3, Water for haemodialysis and related therapies; Part 4: Concentrates for haemodialysis and related therapies; Part 5, Quality of dialysis fluids for haemodialysis and related therapies*; and the revision of the ISO 8637, *Extracorporeal systems for blood purification series standards: Part 1, Haemodialysers, haemodiafilters, haemofilters, and haemoconcentrators, Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters, and haemofilters; and Part 3, Plasmafilters*. Contact: Jill Zajac

AAMI SM-WG03, Interoperability Working Group. The group is seeking general interest, regulatory, and users. The committee is developing a new American National Standard, AAMI SW114 - *Remote control of medical devices: Lung Ventilators and Intravenous (IV) Infusion Pumps*. Contact: Amir Aboutaleb or Matt Williams

AAMI SM-WG05, Medical Device Security Working Group. The group is seeking general interest, regulatory, and users to participate in the revisions of AAMI TIR57:2016/(R)2023, *Principles for medical device security—Risk Management* and a new consensus report (CR) with the title *Security Risk Estimation for Medical Devices.* Contact: Amir Aboutaleb or Matt Williams

AAMI SM-WG06, Wireless Working Group. The group is seeking general interest, regulatory, and users to participate in the reaffirmation of AAMI TIR69:2017/(R)2020 – *Risk management of radio-frequency wireless coexistence for medical devices and systems*. Contact: Amir Aboutaleb or Matt Williams

AAMI SM-WG08, Software Defect Classification Working Group. The group is seeking general interest, regulatory, and users to participate in the reaffirmation of ANSI/AAMI SW91:2018 – *Classification of defects in health software.* Contact: Amir Aboutaleb or Matt Williams

AAMI SM-WG10, Cloud Computing Working Group. The group is seeking user, general interest, and regulatory members to participate in the development of a new TIR, AAMI TIR115: *Cloud – Guidance for the appropriate use of public cloud computing to enable medical device functions*. Contact: Amir Aboutaleb or Matt Williams

AAMI SP, Sphygmomanometer Committee The committee is seeking regulatory, and general interest members to participate in the identical adoption project for ISO 81060-3:2022/Ed.1, *Non-invasive sphygmomanometers — Part 3: Clinical investigation of continuous automated measurement type*. Contact: Ladan Bulookbashi

AAMI ST-WG02, Radiation sterilization working group. The working group is seeking general interest, regulatory, and user members to contribute to development of AAMI CR513/Ed.1, *Guidance on radiation validation and routine maintenance for single-use systems,* reaffirmation of ANSI/AAMI/ISO 11137-2:2013/(R)2019, *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose*. Contact: Mike Miskell.

AAMI ST-WG03, Industrial moist heat sterilization working group. The working group is seeking general interest, regulatory, and user members to participate in the adoption project for ISO 17665:202X (Ed.2), *Sterilization of health care products—Moist heat—Requirements for the development, validation and routine control of a sterilization process for medical devices*. Contact: Mike Miskell.

AAMI ST-WG04, Biological indicators working group. The working group is seeking general interest, regulatory, and user members for the reaffirmation of AAMI/ISO 11138-3, Sterilization of health care products-Biological indicators-Part 3: Biological indicators for moist heat sterilization processes, AAMI/ISO 11138-4, Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes, AAMI/ISO 11138-5, Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes. Contact: Tommy Kim.

AAMI ST-WG08 – Microbiological methods working group. The working group is seeking general interest, regulatory, and user members to participate in the development of AAMI TIR52/Ed.2, *Environmental monitoring for terminally sterilized healthcare products* and the reaffirmation of

AAMI/ISO 11737-1, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*. Contact: Mike Miskell.

AAMI ST-WG16 - Vaporized Hydrogen Peroxide Sterilization working group. The working group is seeking general interest, regulatory, and user members to participate in the national adoption of ISO 22441:2022, Ed. 1, *Sterilization of health care products -- Low temperature vaporized hydrogen peroxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices*. Contact: Mike Miskell.

AAMI ST-WG42 - Dry heat sterilization. The working group is seeking general interest, regulatory, and user members to contribute to participate in the reaffirmation of ANSI/AAMI ST40:2004/(R)2018, Ed. 2, *Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities* and ANSI/AAMI ST50:2004/(R)2018, Ed. 2, *Dry heat (heated air) sterilizers*. Contact: Mike Miskell.

AAMI ST-WG43, Hospital steam sterilizer Working Group. The group is seeking user, general interest, and regulatory members to participate in the development of AAMI ST8/Ed.7, *Hospital steam sterilizers*. Contact: Mike Miskell.

AAMI ST-WG45, Processing of tattoo machines and accessories in healthcare settings Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI TIR117/Ed.1, *Guidance for processing tattoo machines and accessories in the healthcare setting*. Contact: Tommy Kim

AAMI ST-WG86, Quality System for Device Processing Working Group. The group is seeking general interest and regulatory/government members to participate in the amendment of AAMI ST90, *Processing of health care products—Quality management systems for processing in health care facilities.* Contact: Tommy Kim

AAMI ST-WG91, Resistometer Working Group. The group is seeking user, general interest, and regulatory/government members to participate in the reaffirmation of AAMI/ISO 18472:2018, *Sterilization of health care products—Biological and chemical indicators—Test equipment.* Contact: Tommy Kim

AAMI TIB, Transfusion, Infusion, and Injection, and Blood Processing Equipment for Medical and Pharmaceutical Use Committee. The committee and its affiliated working groups are seeking user, industry, and general interest/regulator members to participate in developing the U.S. position towards documents under development in ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, and other projects. Contact: Sam Alameda

AAMI VP, Vascular Prostheses Committee. The committee is seeking user, industry, and general interest/regulator members to participate in the U.S. adoption of ISO 25539-2:2020, *Cardiovascular implants—Endovascular devices—Part 2: Vascular stents;* the revision of ISO 25539-3, *Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters* the revision of ISO 7198 Cardiovascular

implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches Contact: Jill Zajac

UPCOMING MEETINGS

AAMI Committees and U.S. TAGs

Open meetings of AAMI committees and U.S. Technical Advisory Groups (TAGs) are listed here and at the AAMI website (www.aami.org). Note: If you plan to attend a meeting, please send a brief note to the AAMI Standards Department at (standards@aami.org) indicating the name and date of the meeting so that staff can contact you in the event of a last-minute cancellation.

January 2024

AAMI SP, Sphygmomanometer committee (open meeting) 30 January 2024, 12:30h to 14:00h EST, web meeting. The committee meets bimonthly to obtain updates on the activities of ISO/TC 121/SC 3-IEC/SC 62D Joint WG7, Non-invasive blood pressure monitoring equipment. Contact: Ladan Bulookbashi

AAMI ST-WG02, Radiation Sterilization Working Group (open meeting) 30 and 31 January 2024, 14:00h to 17:00h EST, web meeting. The WG will determine comments to forward with the US position to the US TAG on the Systematic Review ballot of ISO 11137-2:2013, *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose*. Contact: Mike Miskell

February 2024

AAMI ST-WG02, Radiation Sterilization Working Group (open meeting) 1 February 2024, 11:00h to 14:00h EST, web meeting. The WG will continue work on the Systematic Review ballot of ISO 11137-2:2013, *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose*. Contact: Mike Miskell

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group (open meeting) 15 February 2024, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Mike Miskell

AAMI TIB-WG04, Elastomeric parts, components and packaging working group (open meeting) 21 February 2024, 10:00h to 11:00h EST, web meeting to discuss/develop CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD).* Contact: Sam Alameda

AAMI EQ-WG01, HTM Program Management Working Group (open meeting) 26 February 2024, 14:00h to 16:00h EST, web meeting. The WG will resolve comments on the revision of AAMI EQ56:2013, *Recommended practice for a medical equipment management program*. Contact: Mike Miskell

INTERNATIONAL STANDARDS

Information on draft international standards under ballot can be found in ANSI Standards Action.

International Committee and Working Group Meetings

Call or email the indicated staff person at AAMI for more information about upcoming international standards meetings.

January 2024

ISO/TC 150/SC 2/WG 2, Circulatory Support Devices (closed meeting). Virtual 26 January 2024, 09:30h to 10:30h EST. Contact: Jill Zajac

February 2024

ISO/TC 121/SC3, Respiratory devices and related equipment used for patient care and JWG12 (closed meetings). Sydney, Australia, 5-9 February 2024. Contact: Colleen Elliott

ISO/TC 210/AHG 3, Review of handbook for ISO 13485 (closed meeting). Virtual, 1 February 2024, 07:00h to 09:00h CST. Contact: Amanda Benedict

ISO/TC 210/WG 1, Application of quality systems to medical devices (closed meeting). Virtual, 7 February 2024, 06:00h to 07:30h CST. Contact: Amanda Benedict

ISO/TC 198/WG 9, Aseptic processing (closed meeting). Virtual, 13 February 2024, 11:00h to 15:00h CET. Contact: Amanda Benedict

March 2024

ISO/TC 210/JWG 1, Application of risk management to medical devices (closed meetings). Arlington, Virginia, USA, 6-8 March 2024, 09:00h to 17:00h daily local time. Contact: standards@aami.org

April 2024

IEC/SC 62A, Common aspects of medical equipment, software, and systems, and affiliated WGs (closed meetings). Arlington, Virginia, USA, April 24 – May 3, 09:00h to 17:00h daily local time. Contact: celliott@aami.org.

May 2024

ISO/TC 121, Anaesthetic and respiratory equipment, and affiliated SCs and (J)WGs (closed meetings). Luebeck, Germany, May 13 – 17, 09:00h to 17:00h daily local time. Contact: celliott@aami.org.

October 2024

IEC/TC 62, Medical equipment, software, and systems, and affiliated SC and (J)WG meetings (closed meetings). London, UK, 14-18 and Edinburgh, Scotland, 21-25 October 2024, 09:00h to 17:00h daily local time. Contact: Colleen Elliott or Ladan Bulookbashi